are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Evaluation of the Chronic Disease Self-Management Program in the US Affiliated Pacific Islands (OMB Control No. 0920–1265, Exp. 06/30/2021)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCCDPHP is evaluating the implementation of Stanford University's Chronic Disease Self-Management Program (CDSMP) in the US Affiliated Pacific Islands (USAPI). These jurisdictions include American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia.

The purpose of the evaluation is to understand how CDSMP is being implemented in the region, to identify barriers and facilitators to implementation, to monitor fidelity to Stanford University's model and document adaptations to the curriculum, and to understand the self-reported effects of the program on program participants. Because this is the first time CDSMP is being implemented in the USAPI, we do not know if the intervention, which has proven to improve health outcomes in many ethnic groups within the United States, will lead to improved health outcomes for these communities.

Collecting this data helps us assess fidelity to and adaptations to the intervention and to understand if CDSMP, an evidence-based intervention, has the same effect in the US Affiliated Pacific Islands as it has in multiple ethnic groups within the United States. CDC requests OMB approval for an estimated 95 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Program Participant	Chronic Disease Self-Management Workshop Evaluation.	190	1	10/60	32
Program Participant	Chronic Disease Self-Management Questionnaire (Pre-Post Test).	190	2	10/60	63
Total					95

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; OPRE Data Collection for Supporting Youth To Be Successful in Life (SYSIL) (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting approval from the Office of Management and Budget (OMB) for a new data collection. The Supporting Youth to be Successful in Life study (SYSIL) will build evidence on how to end homelessness among youth and young adults with experience in the child welfare system by continuing work with an organization who conducted foundational work as part of the Youth At-Risk of Homelessness project (OMB Control Number: 0970–0445). SYSIL will provide important information to the field by designing and conducting a federally led evaluation of a comprehensive service model for youth at risk of homelessness.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The SYSIL evaluation includes an implementation study and an impact study, which will use a rigorous quasi-experimental design that includes a comparison group. This new information collection request includes the baseline and follow-up survey instruments for the impact study (a single instrument administered four times), and discussion guides for interviews and focus groups for the implementation study. The data collected from the baseline and follow-up surveys will be used to describe the characteristics of the study sample of youth, develop models for estimating program impacts, and determine program effectiveness by comparing outcomes between youth in the treatment (youth receiving the Pathways program) and control groups. Data from the interviews and focus groups will provide a detailed understanding of program implementation. We will also conduct brief check-ins with program directors using a subset of questions from the interview guides to collect information on services provided at two additional points in time. The study will also use administrative data from the child welfare system, homelessness management information system, and program providers. Administrative data will be used in its existing format and does not impose any new information collection or recordkeeping requirements on respondents.

Respondents: The baseline and follow-up surveys will be administered to youth in the treatment group (youth receiving the Pathways program) and youth in the control group who consent to participate in the study. Interviews will be conducted with program leadership and staff. Focus groups will be conducted with a subset of youth who are participating in the study. Check-ins will be conducted with program directors.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
SYSIL Youth Survey—Baseline survey	700	1	.5	350	117
SYSIL Youth Survey—Follow-up survey 1 (6 months)	630	1	.5	315	105
SYSIL Youth Survey—Follow-up survey 2 (12 months)	595	1	.5	298	99
SYSIL Youth Survey—Follow-up survey 3 (24 months)	490	1	.5	245	82
Interview guide for Pathways sites (treatment sites)	30	1	1.5	45	15
Program Director Check-ins for Pathways sites (treatment sites)	6	2	.5	6	2
Interview guide for comparison sites	30	1	1.5	45	15
Program Director Check-ins for comparison sites	6	2	.5	6	2
Focus group discussion guide for Pathways youth (treatment youth)	50	1	1.5	75	25
Focus group discussion guide for comparison youth	50	1	1.5	75	25

Estimated Total Annual Burden Hours: 487.

Authority: Section 105(b)(5) of the Child Abuse Prevention and Treatment Act (CAPTA) of 1978 (42 U.S.C. 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Medical Devices; Class I Surgeon's and Patient Examination Gloves

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice; request for comments.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') issued a Notice in the **Federal Register** of January 15, 2021, that, among other things, identified seven types of reserved class I devices that the Department had determined no longer require premarket notification. The Department and the Food and Drug Administration (FDA or ''the Agency'') have reviewed the prior determination, including the record supporting it, and believe that the determination is flawed. This notice explains the basis for HHS and FDA's current view that the seven types of reserved class I devices identified in the January 15, 2021, Notice require a premarket notification, and explains why the reasoning supporting the prior determination was unsound. HHS and FDA are seeking comment on the matters discussed in this notice and will issue a future notice in the **Federal Register** containing a final determination regarding the class I medical gloves listed in the January 15, 2021, Notice.

DATES: Submit either electronic or written comments on this Notice by May 17, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted by May 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–Z–0025 for ''Medical Devices; Class I Reserved Surgeon's and Patient Examination Gloves.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the